# MULTI-DRUG SYSTEM FOR DETECTING AND TREATING CHEMICAL AND BIOLOGICAL AGENTS

## REFERENCE TO PREVIOUS APPLICATIONS

This application claims the benefit of United States Provisional Applications No. 60/449,099 filed on February 24th, 2003.

## FIELD OF THE INVENTION

The present invention relates generally to the field of chemical detection and drug delivery systems. More particularly, the invention relates to a system that can both sense chemical and biological warfare agents, and deliver an antidote from an inventory of multiple drugs contained in the system.

## BACKGROUND OF THE INVENTION

The threat of biological attack from terrorists or rouge states has increased in recent years. Biological threats put soldiers, sailors, law enforcement, emergency response and postal personnel, etc., at risk. In addition to biological threats, chemical agents pose a danger to military personnel, as well as first responders and civilians. The disclosed system could serve as a rapid, personnel treatment system for both biological and chemical attack. Many of the potential chemical agents require immediate treatment to save the victim's life. A selection of

more than a dozen different chemical or biological agents is available to state-sponsored terrorists. While not all biochemical agents have antidotes, a significant percentage does. For example, antidotes and treatments exist for Sarin, VX, Tabun, Soman, Cyanide, Lewisite, Anthrax, Brucellosis, Plague, Q fever and Botulism. Making treatment available in the field, in time to be effectively used is a problem. Treatment on a remote battlefield, especially when fast acting chemical agents are involved is also difficult since many affected personnel maybe incapacitated. This invention comprises of a new system that will be capable of delivering multiple antidotes for a wide variety of biochemical agents. This personal protection system could be automated to ensure proper utilization by incapacitated victims.

## SUMMARY OF THE INVENTION

The invention comprises a system that can (1) sense chemical and biological warfare agents, (2) deliver an antidote from an inventory of multiple drugs contained in the system or (3) both sense chemical and biological warfare agents and deliver an antidote from an inventory of multiple drugs contained in the system. The system is portable and can be used for armed forces, social service providers (for example, fire fighters, police, FBI, etc.), or civilians as an effective means for protection against chemical or biological attacks.

One preferred method is to use micromachined devices (also known as microelectromechanical systems: MEMS) to fabricate one or more system elements such as the pump, sensor, drug metering system and injection device. The advantage of using MEMS is that it allows devices that are small, low power, rugged, biocompatible, and low cost at high volume. The drug delivery portion of this system may contain multiple drug reservoirs (preferably small size and potent), which can be instructed (programmed) either by the user, by a radio signal from a central location, or by one or more sensors within the portable system.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a picture of a mock drug delivery system with multiple drug reservoirs.

Figure 2 is a block diagram of a single antidote drug delivery system.

## DETAILED DESCRIPTION OF PREFERRED AND ALTERNATE EMBODIMENTS OF THE INVENTION

The following description of preferred embodiments and methods provides examples of the present invention. The embodiments discussed herein are merely exemplary in nature, and are not intended to limit the scope of the invention in any manner. Rather, the description of these preferred embodiments and methods serves to enable a person of ordinary skill in the relevant art to make, use and perform the present invention.

The threat of biological and chemical (biochem) attack from terrorists or rouge states has increased in recent years. Biochem threats put soldiers, sailors, law enforcement, emergency response and postal personnel at risk. Unfortunately, no combination of commercial or military products or system solution is in place that can provide immediate and effective defense against an actual chemical/bio attack. The medical response time to an actual attack is of paramount importance, which can make the difference between complete recovery or death and/or permanent handicap. Making treatment available in the field, in time to be effectively used is a problem. Treatment on a remote battlefield, especially when fast acting chemical agents are involved is also difficult since many affected personnel maybe incapacitated.

Many of the potential chemical agents require immediate treatment to save the victim's life. A selection of more than a dozen different chemical or biological agents is available to state-sponsored terrorists. While not all biochem agents have antidotes, a significant

percentage does. For example, antidotes and treatments exist for Sarin, VX, Tabun, Soman, Cyanide, Lewisite, Anthrax, Brucellosis, Plague, Q fever and Botulism.

The present invention provides a portable, rapid-response bio-protection system as an early defense for individuals against chemical and biological terrorist attacks. This system is capable of performing one or more or a combination of the following operations:

- Detection of the type and amount of the used chemical agent,
- Selection of an appropriate antidote combination from multiple reservoirs in the device
- Preparation and mixing the antidote from the correct selected chemicals and at the right concentration, and
- Delivery of such custom-mixed antidote with high accuracy.

In the preferred embodiment, the system has up to four major parts: (1) Detectors and sensors (2) Intelligence to select proper amount and combination from the multiple high-potency antidotes in the system, (3) Fluidic Controller, including extremely accurate drug flow measurements, mixing of multiple drugs at micro-liter level, and flow control; and (4) multiple reservoirs of antidotes.

The system can incorporate several sensors/detectors **10**, reservoirs of multiple antidotes **20**, and antidote drug delivery devices into an effective small-size, portable system that can be carried as standard equipment and quickly (manually or automatically) use during an attack. Micromachined devices (also known as microelectromechanical systems or MEMS) can be used to fabricate one or more of the system elements, such as the sensors, the drug metering systems, the pump and the injection device. These MEMS devices are small, low power, rugged, biocompatible and can be manufactured at a low cost in high volumes. As shown in Figure 1, multiple drug/antidote reservoirs **20**, can be linked to a single manifold **30**.

The basic single antidote infusion system is shown in Figure 2. One or more drug infusion reservoir **110** are connected to the MEMS mass flow sensors **120** and valves **130** which

are then connected to the drug outlet **160**. The drug reservoir **110** can be pressurized with elastomeric walls or a spring. Alternatively, electric pumps can be used. Each cartridge is connected to both a fluid and electrical manifold. Since the system is modular, the size of the drug reservoir **110** can vary to accommodate different dosing requirements. The electrical manifold **140** provides power to the sensors **120** and valves **130**, output signals from the sensors **120** and input signals to the valves **130**. The system must draw relatively little power and operate using batteries for extended periods of time. A central microprocessor **150** with external communicated inputs (for example keypad or radio signal) will control the infusion system. Chemical sensors or other communication inputs will instruct the unit as to which and how much drug to inject into the user. The system also has the ability to set off an alarm and/or output data **170.** As mentioned previously, the preferred embodiment will incorporate several sensors/detectors, reservoirs of multiple antidotes, and antidote drug delivery devices into an effective small-size, portable system.

The multiple drug delivery devices in the system can be instructed or programmed either by the user, by a radio signal from a central location, or by one or more sensors within the portable system. This programmability includes, but is not limited to, the drug combinations to be delivered, the dosage of each drug, and the timing of the drug delivery (for example continuous or intermittent). The drug delivery can be accomplished using a variety of methods including but not limited to manual pumps, integrated pumps, valves, micro-valves, etc. The system is also capable of measurements including but not limited to measuring the amount of drug flow per second, measuring the accumulated amount of delivered drugs, measuring the drug density, and other such measurements. In addition, the system is capable of mixing more than one drug and delivering the controlled drug mixture.

The system may offer other functions such as global positioning system (GPS), sending alert signals in the event of detecting a chemical or biological attack, monitoring the user's

biological functions (for example, heartbeat), sending such information to other centers or users, etc.

In the preferred embodiment, the system contains both the detection and drug delivery portions in the same portable unit. However, systems without the detection capability are also very useful and are covered under this invention disclosure. The system will automatically respond to a sensed chemical or biological threat and deliver the appropriate antidote to the user. A central, remote detection device can be linked through a wireless radio network with one or more multi-drug delivery systems. Each multi-drug delivery system can receive a message from the central detection system and select the antidote and deliver the required drug combination, dose, and delivery timing for the user wearing the system. An alternative method can have each device using a keypad for the user to interface with the multi-drug delivery system. When the user is instructed that exposure to a chemical or biological agent has occurred, the user can punch in the appropriate code and the correct antidote will be delivered to the user.

In the preferred embodiment, after a chemical or biological attack is detected, the user can activate the drug delivery option and put the antidote delivery system (for example needle) of the drug delivery system into his/her body and allow the system to deliver the right drug combination and dosage. In an alternative embodiment, in highly risky situations (for example in a risky battlefield situation, or a known contaminated field) an antidote delivery system (for example needle or a catheter) can be already attached to the user's body and the system will inject the proper drugs without any (or minimal) direct interference from the user. The antidote delivery path for each embodiment can include but is not limited to one or more of the following: intravenous, intraarterial, subcutaneous, transdermal, intradermal, intramuscular, manual injection by the user or medical personnel.

The disclosed portable delivery system can be used for a variety of other applications if instead of (or in addition to) the previously mentioned antidotes other drugs or chemical are used. These additional applications include but not limited to one or more or any combination of the following applications:

- Performance Enhancement System
- Prolonged Performance and Functionality System
- Survival System (e.g., for war, terrorist attacks, bombs, etc. or natural disasters such as earth quake, avalanche, etc.)
- Immediate Emergency Treatment System
- Remote Emergency Treatment System

The foregoing disclosure includes the best mode devised by the inventors for practicing the invention. It is apparent, however, that several variations in the apparatuses and methods of the present invention may be conceivable by one skilled in the art. Inasmuch as the foregoing disclosure is intended to enable one skilled in the pertinent art to practice the instant invention, it should not be construed to be limited thereby, but should be construed to include such aforementioned variations.